

CLAIMS

1. A pharmaceutical composition comprising (i) a compound selected from the group consisting of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione and a pharmaceutically acceptable salt thereof, and (ii) one or more of a pharmaceutically acceptable carrier or excipient, wherein said mixture has a water content below about 1%(w/w).
2. The composition of claim 1 in the form of a tablet, a powder or a capsule.
3. The composition of claim 1, further comprising an antioxidant.
4. The composition of claim 3, wherein said antioxidant comprises between 1 and 100 parts by weight and the pharmaceutically acceptable excipient is selected from the group consisting of:
 - between 100 and 400,000 parts by weight of anhydrous lactose,
 - between 1 and 100 parts by weight of an antioxidant,
 - between 50 and 500 parts by weight of pregelatinized starch,
 - between 1000 and 10,000 parts by weight of microcrystalline cellulose,
 - between 10 and 500 parts by weight of crospovidone,
 - between 10 and 500 parts by weight of silicon dioxide,
 - between 10 and 500 parts by weight of hydrogenated vegetable oil,
 - between 10 and 500 parts by weight of magnesium stearate,
 - between 10 and 500 parts by weight of hydroxypropyl methylcellulose,
 - between 10 and 500 parts by weight of hydroxypropyl cellulose,
 - between 1000 and 10,000 parts by weight of mannitol,
 - between 10 and 500 parts by weight of stearic acid, or
 - between 10 and 500 parts by weight of titanium dioxide.
5. The pharmaceutical composition of claim 1, wherein the water content is below about 0.5% (w/w).
6. The pharmaceutical composition of claim 5, wherein the water content is below about 0.1% (w/w).

7. The pharmaceutical composition of claim 6, wherein water content is below about 0.05% (w/w).
8. The composition of claim 3, wherein the antioxidant is selected from group consisting of: α -tocopherol, γ -tocopherol, δ -tocopherol, extracts of natural origin rich in tocopherol, L-ascorbic acid and its sodium or calcium salts, ascorbyl palmitate, propyl gallate (PG), octyl gallate, dodecyl gallate, butylated hydroxy anisole (BHA), and butylated hydroxy toluene (BHT).
9. The composition of claim 8, wherein the antioxidant is α -tocopherol.
10. The pharmaceutical composition of claim 1, further comprising at least one customary additive selected from the group consisting of sweeteners, flavouring agents, colours and lubricants.
11. The composition of claim 1 comprising (i) a compound selected from the group consisting of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiadiazolidine-2,4-dione and a pharmaceutically acceptable salt thereof, and (ii) pharmaceutically acceptable excipients comprising anhydrous lactose, microcrystalline cellulose, magnesium stearate, and talc.
12. The composition of claim 11, wherein the pharmaceutically acceptable excipients are: between 100 and 400,000 parts by weight of anhydrous lactose, between 1000 and 10,000 parts by weight of microcrystalline cellulose, and between 10 and 500 parts by weight of magnesium stearate, expressed in parts by weight per 100 parts of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiadiazolidine-2,4-dione, or of one of its pharmaceutically acceptable salts.
13. The composition of claim 12, wherein the amount of talc is 0-10% (weight/weight).
14. The composition of claim 1, comprising:
- | | |
|--|-----|
| 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt | 9% |
| cellulose microcrystalline | 20% |
| lactose | 66% |

magnesium Stearate	0.5%
talc	4.5%

15. The composition of claim 1, comprising:

5	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	18%
	cellulose microcrystalline	20%
	mannitol	57%
	magnesium stearate	0.5%
10	talc	4.5%

16. The composition of claim 1, comprising:

	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	18%
15	lactose	81.5%
	magnesium stearate	0.5%

17. The composition of claim 1, comprising:

	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	0.09%
20	mannitol	98%
	magnesium stearate	2%

18. The composition of claim 1, comprising:

25	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	0.09%
	hydrogenated vegetable oil	6.25%
	talc	5%
	α -tocopherol	50% of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-
30	quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	
	lactose DCL21/mannitol	Up to 200 g.

19. The composition of claim 1, comprising:

	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione, potassium salt	0.09%
35	povidone	7.5%

	hydroxypropylmethyl cellulose	1.5%
	croscarmellose sodium	1.56%
	talc	1.1%
	magnesium stearate	0.5%
5	lactose 300 mesh	up to 200 g.

20. The composition of claim 1, comprising the following:

	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-	
	dione, potassium salt	0.1096 g
10	mannitol	2.5 g
	hydroxypropyl- β -cyclodextrin	10 g
	and diluted with 92 mL water before use.	

21. The composition of claim 1, comprising:

15	5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-	
	dione, potassium salt	1.096 g
	mannitol	2.5 g
	hydroxypropyl- β -cyclodextrin	10 g
	sodium carbonate, anhydrous,	
20	Na ₂ CO ₃	15 mg
	and diluted with 92 mL water before use.	